DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

94734d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

WARNING LETTER

NWE-24-04W

April 7, 2004

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Irving A. Salkovitz, D.V.M.
Wadleigh's Falls Veterinary Clinic
8 Campground Road
Lee, New Hampshire 03824

Dear Dr. Salkovitz:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in a dairy cow that originated from [redacted]. An investigation of your veterinary medical practice located in Lee, New Hampshire on January 27, 2004 by the FDA revealed serious deviations from the Extralabel Drug Use in Animals regulations (Title 21, Code of Federal Regulations, Part 530). Such deviations cause veterinary drugs prescribed by you to be adulterated within the meaning of section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found that the gentamicin vials you dispensed to [redacted] were responsible for the illegal tissue residue in a cow offered for slaughter for human food. Further, the gentamicin vials you dispensed to [redacted] came without any written labeling instructions, such as, your name and address and directions for use. The extralabel use of gentamicin in dairy cows may only be done in compliance with 21 CFR Part 530, Extralabel Drug Use in Animals. These regulations require, among other conditions, that:

1) Prior to prescribing or dispensing an approved new animal drug for an extralabel use in food animals, the veterinarian must:
   a) Establish a substantially extended withdrawal period prior to marketing of milk, meat, eggs, or other edible products supported by appropriate scientific information.
   b) Institute procedures to assure that the identity of the treated animal or animals is carefully maintained.
   c) Take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food producing animal subject to extralabel treatment.

2) The new animal drug prescribed or dispensed for extralabel use must bear or be accompanied by labeling information which is adequate to assure the safe and proper use of the product. At a minimum, the following label information is required:
   a) The name and address of the prescribing veterinarian.
   b) The established name of the drug (active ingredient), or if formulated from more than one ingredient, the established name of each ingredient.
   c) Any directions for use specified by the veterinarian (including the class/species or identification of the animal or group of animals; and the dosage, frequency, route of administration, and duration of therapy).
   d) Any caution statements.
   e) The veterinarian's specified withdrawal/discard time(s) for meat, milk, eggs, or any other food which might be derived from the treated animal(s).

We request that you take prompt action to ensure that when you prescribe new animal drugs for extralabel use, you do so in accordance with the above requirements, and any other applicable requirements of 21 CFR Part 530.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action, including seizure and/or injunction.

You should notify our office in writing within fifteen (15) working days of receiving this letter of the specific steps you have taken to correct these violations and prevent their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed.

Your response should address each discrepancy brought to your attention and demonstrate that corrections have been made. Please direct your reply to Bruce R. Ota, Compliance Officer, US Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180.

Sincerely,

Gail T. Costello
District Director
New England District

cc: New Hampshire Board of Veterinary Medicine
25 Capitol Street
Box 2042
Concord, New Hampshire 03302-2042
Attn: Patricia Duncklee, Administrative Secretary